PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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- 8 FEB 2005

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	03.02.2005
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
P61826PC00	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 03/00761	03.11.2003	01.11.2002

Applicant
POLYGANICS B.V. et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P61826PC00	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/NL 03/00761	International filing date *(day/month/year)* 03.11.2003	Priority date *(day/month/year)* 01.11.2002
International Patent Classification (IPC) or both national classification and IPC A61L29/14		
Applicant POLYGANICS B.V. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.05.2004	03.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Heck, G Telephone No. +31 70 340-3288

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00761

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-27 as originally filed

Claims, Numbers

1-40 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 36-39

   because:

   ☒ the said international application, or the said claims Nos. 36-39 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-35, 40
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-35, 40
Industrial applicability (IA)	Yes:	Claims	1-35, 40
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Since claims 36-39 are directed to a method of treatment of the human or animal body by surgery, they relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. For the assessment of the subject-matter of present claims 36-39 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States.
Therefore, no opinion will be formulated with respect to the subject-matter of claims 36-39 (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D1 and D2) cited in the International search report are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US 5,201,724 A (Hukins David W. et al.)
D2: US 5,129,889 A (Hahn John L. et al.)

Novelty

Document D1 discloses (cf. col. 1, line 67 - col. 3, line 13) a medical catheter suitable for the drainage of body fluids, comprising a biodegradable polymer, e.g. in form of a layer.
Document D2 (cf. col. 2, lines 26-63 ; claims 1-6) discloses an epidural catheter comprising a synthetic absorbable polymer (polymers of dioxanone, caprolactone, glycolide and lactide).

The subject-matter of claims 1-35 and 40 of the present application differs from D1 and D2 in that the biodegradable synthetic polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature and is therefore novel according to Article 33(2) PCT.

Inventive Step

Document D1, which is considered to represent the most relevant prior art, discloses (cf. col. 1, line 67 - col. 3, line 13) the use of a biodegradable polymer on a drainage catheter to prevent the problems occurring in indwelling catheters, especially in terms of resisting infection, encrustation and blockage.

In view of D1, the objective technical problem underlying the present application is to provide an alternative drain which does not lead to complications such as irritation, inflammatory response or removal problems.

The solution according to the present application is a drain comprising a biodegradable synthetic polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature.

The difference between the subject-matter of claim 1 and D1 is the softening point (glass transition temperature) of the biodegradable synthetic polymer of at most mammalian body temperature, whereas it is unspecified in D1. A low glass transition temperature of the polymer leads to elasticity and flexibility of the drain.

For the skilled person, the use of a polymer having a softening point of at most mammalian body temperature to obtain sufficient elasticity and flexibility is an obvious choice among several available possibilities, so that no inventive step can be acknowledged for the subject-matter of claim 1-3 of the present application.

The choice of the polymers mentioned in dependent claims 4-26 comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance. For that reason, the subject-matter of the dependent claims 4-26 lacks an inventive step (Article 33(3) PCT).

The shape and the dimensions of the drain of the present application mentioned in claims 29, 33 and 34 do not contribute to the solution of the technical problem, so that the subject-matter of claims 29, 33 and 34 cannot be considered to involve an inventive step according to Article 33(3) PCT either.

The use of a drain in the preparation of a medicament for the treatment of specific disorders according to claim 40 does not present any particular or surprising effect compared to its use for other disorders. Consequently, the subject-matter of claim 40 cannot be considered to involve an inventive step (Article 33(3) PCT).

The subject-matter of claims 1-35 and 40 of the present application is considered to be industrially applicable according to Article 33(4) PCT.